WHAT IS CLAIMED IS:

1. A method for generating immune cells, comprising:

collecting material comprising body fluid or tissue containing mononuclear cells from a mammal; and

contacting, in the absence of exogenous interleukin-2, the material with one or more activating proteins specific for cell surface proteins present on cells in the material and in an amount sufficient to induce ex vivo cell expansion, whereby the cells expand to clinically relevant numbers.

2. The method of claim 1, wherein prior to the contacting step, the cells in the material are treated under conditions whereby ex vivo differentiation of some or all of the cells into selected regulatory immune cells is induced.

3. The method of claim 1, wherein during the contacting step, the cells in the material are treated under conditions, other than addition of exogenous IL-2, whereby ex vivo differentiation of some or all of the cells into desired effector immune cells is induced.

4. The method of claim 1, wherein the expanded cells are purified.

5. The method of claim 2, wherein the expanded cells are purified.

6. The method of claim 1, wherein the immune cells are specific for a defined antigen.

7. The method of claim 2, wherein the immune cells are specific for a defined antigen.

8. The method of claim 1, wherein the expanded cells are predominantly Th1, Th2 or Th3 cells.

9. The method of claim 1, wherein the immune cells are activated ex vivo prior to the contacting step in the presence of either or

both interferon-γ and IL-2, whereby differentiation of Th1 cells are effected.

10. The method of claim 1, wherein the cells are activated ex vivo in the presence of one or more of an agent selected from IL-4, anti-gamma interferon and anti-IL-12, whereby differentiation of Th2 cells is effected.

11. The method of claim 1, wherein the proteins specific for cell surface molecules are one or more monoclonal antibodies specific for immune cell surface proteins.

12. The method of claim 11, wherein the monoclonal antibodies are specific for CD3 or CD2, combined with any combination of one or more of the following: CD4, CD8, CD11a, CD27, CD28, CD44 and CD45RO.

13. The method of claim 1, wherein expansion is effected in a hollow fiber bioreactor.

14. The method of claim 1, wherein the immune cells are expanded to an excess of 10^9 cells.

15. The method of claim 1, wherein the immune cells are expanded to an excess of 10^{10} cells.

16. The method of claim 1, wherein the cells are effector immune cells.

17. The method of claim 1, wherein the cells are regulatory immune cells.

18. A method for autologous cell therapy, comprising:

collecting material comprising body fluid or tissue containing mononuclear cells from a mammal; and

contacting, in the absence of exogenous interleukin-2, the material with one or more activating proteins specific for cell surface proteins present on cells in the material and in an amount sufficient to induce ex

vivo cell expansion, whereby the cells expand to clinically relevant numbers; and

infusing the resulting cells into a mammal.

19. The method of claim 18, wherein expanded cells are purified prior to infusion into the mammal.

20. The method of claim 18, wherein the expanded cells are regulatory immune cells.

21. The method of claim 18, wherein the expanded cells are effector immune cells.

22. A method for generating regulatory immune cells, comprising:

collecting material containing mononuclear cells from a mammal;

treating the cells to alter their cytokine production profile; and

expanding the cells to a clinically relevant number of cells.

23. The method of claim 22, wherein the immune cells with altered cytokine profile are purified prior to infusion.

24. The method of claim 22, wherein the immune cells with altered cytokine profile are specific for a defined antigen.

25. The method of claim 23, wherein the immune cells with altered cytokine profile are specific for a defined antigen.

26. The method of claim 22, wherein the mononuclear cells are treated to differentiate into Th1 or Th2 cells.

27. The method of claim 22, wherein the resulting population of cells are Th1-like or Th2-like cells.

28. The method of claim 22, wherein the immune cells are activated ex vivo in the presence of either or both interferon-γ and IL-2, whereby differentiation of Th1 cells is effected.

29. The method of claim 28, wherein anti-IL-4 mAb is also present during activation.

30. The method of claim 29, wherein the effector cells are activated in the presence of IL-4 or IL-4 and either or both anti-gamma interferon and anti-IL-12 antibodies, whereby differentiation of Th2 cells is effected.

31. The method of claim 22, wherein one or more monoclonal antibodies are included in the medium in which the mononuclear cells are expanded.

32. The method of claim 31, wherein the monoclonal antibodies are specific for CD3 or CD2, combined with any combination of one or more of the following: CD4, CD8, CD11a, CD27, CD28, CD44 and CD45RO.

33. The method of claim 22, wherein the cells are expanded in a hollow fiber bioreactor.

34. The method of claim 22, wherein the cells are expanded to an excess of 10^9 cells.

35. The method of claim 22, wherein the cells are expanded to an excess of 10^{10} cells.

36. A method of producing virally purged $CD4^+$ cells, comprising:

isolating $CD4^+$ cells from a patient infected with human immunodeficiency virus (HIV);

contacting the cells with one or more protein activating agents;

selecting cells $CD4^+$ that are HIV^-; and

then expanding the selected cells to clinically relevant numbers.

37. The method of claim 36, wherein in the contacting step, the activating under conditions promote Th1 cell differentiation.

38. The method of claim 36, further comprising:

after selecting $CD4^+$ that are HIV^- and prior to expanding the selected cells, growing a plurality of aliquots in the presence of mitogenic agents;

selecting from the aliquots those that are HIV^-; and

then expanding the selected cells to clinically relevant numbers.

39. The method of claim 36, wherein the cells are activated with anti-CD3 mAb in the presence of interferon-γ (IFN-γ).

40. The method of claim 38, wherein, after activation, the cells are grown in the presence of anti-CD28 mAb and IFN-γ.

41. The method of claim 1, wherein the cells are $CD8^+$ cells.

42. A composition, comprising a clinically relevant number of $CD4^+$ cells.

43. A composition comprising virally purged $CD4^+$ cells produced by the method of claim 36.

44. The composition of claim 42, wherein the $CD4^+$ cells are predominantly Th1-cells.

45. A combination, comprising:

a composition containing a clinically relevant number of virally-purged $CD4^+$ cells; and

a composition containing a clinically relevant number of $CD8^+$ effector cells.

46. A method of treating a patient infected with HIV, comprising:

administering a clinically relevant number of virally-purged $CD4^+$ cells.

47. The method of claim 46, further comprising administering a clinically relevant number of $CD8^+$ effector cells, wherein the effector cells are administered, before, after or simultaneously with the $CD4^+$ cells.

48. A method of treating patients with autologous immune cells, comprising:

collecting a tissue or body fluid sample comprising mononuclear cells from a mammal;

treating the cells ex vivo to produce compositions containing clinically relevant number of regulatory immune cells; and

reinfusing a sufficient number of the cells to alter the in vivo regulatory immune cell balance.

49. The method of claim 48, wherein the cells are treated to differentiate into Th2-like cells.

50. The method of claim 49, wherein the patients are diagnosed with an autoimmune disease or disease characterized by chronic inflammation.

51. The method of claim 48, wherein the cells are treated to differentiate into Th1-like cells.

52. The method of claim 51, wherein the patients are diagnosed with allergic disorders or infectious disease.

53. The method of claim 48, wherein the patients are to receive an organ or tissue transplant from an allogeneic or xenogeneic donor.

54. The method of claim 51, wherein the immune cells are exposed to one or more antigens from one or more pathogenic organisms and reinfused to protect the patient from subsequent infection from the same pathogens.

55. A composition, comprising a clinically relevant number of human regulatory T-cells

56. The composition of claim 55, wherein the cells are contained in a volume of one liter or less.

57. The composition of claim 55, wherein the cells are contained in a volume of 500 mls or less.

58. The composition of claim 57, wherein the volume is 250 mls or less.

59. The composition of claim 55, wherein the concentration of cells is at least about 10^7-10^8 cells/ml.

60. A combination, comprising:

a composition of claim 55; and

a composition comprising a clinically relevant number of human effector T-cells.

61. The combination of claim 60, wherein the concentrations of human regulatory cells and human effector cells are each at least about 10^7-10^8 cells/ml.

62. The combination of claim 60, wherein the compositions are mixed.

63. The composition of claim 56, wherein the cells are human effector T-cells.

64. The composition of claim 55, comprising at least 10^9 regulatory immune cells.

65. The composition of claim 64, comprising at least 10^{10} cells.

66. The composition of claim 64, wherein the cells are Th1 cells.

67. The composition of claim 64, wherein the cells are Th2 cells.

68. A method for treating autoimmune disease, comprising administerting an therapeutially effective amount of the composition of claim 55, wherein the amount is sufficient to treat the automimmune disease.

69. The method of claim 68, wherein the disease is selected from rheumatoid arthritis, inflammatory bowel disease (IBD) or to prevent transplant rejection.

70. A method of preventing rejection of transplanted islets for treatment of insulin-dependent diabetes mellitus (IDDM), comprising: administering a therapeutically effective amount of the composition of, claim 55, wherein the amount is sufficient to prevent rejection of transplanted islets of Langerhans for the treatment of IDDM.

71. A method for treating treating allergies, infectious disorders or diseases, tumors or as vaccinating a human, comprising: administering a therapeutically effective amount of the composition of, claim 55, wherein the amount is sufficient to treat the allergy, infectious disorder, tumor or to protect the human against infection or ameliorate the severity of an infection.

72. A composition of claim 55, comprising at least 10^9 Th3 cells.

73. A method of treatment of treating multiple sclerosis or insulin-dependent diabetes mellitus (IDDM), comprising: administering a therapeutically effective amount of the composition of, claim 55, wherein the amount is sufficient to treat multiple sclerosis or IDDM.

74. A method for treating autoimmune disorders, comprising administering a composition containing a therapeutically effective number of regulatory immune cells, whereby the symptoms of the disease are ameliorated or progression of the disease is retarded.

75. The method of claim 74, wherein the disease is rheumatoid arthritis, multiple sclerosis, insulin-dependent diabetes mellitus, or inflammatory bowel disease.

76. The method of claim 74, wherein the population of immune cells is Th2-like.

77. The method of claim 74, wherein the number of regulatory immune cells is at least 10^9.

78. The method of claim 77, wherein the cells are contained in a volume of 1 liter or less.

79. The method of claim 74, wherein the disease is rheumatoid arthritis, wherein the composition is produced by a method comprising:

collecting mononuclear cells from a rheumatoid arthritis patient;

expanding the cells under conditions whereby a composition containing an amount of Th2 cells sufficient to suppress or reduce the chronic inflammatory lesions of the arthritis; and

infusing the resulting composition of cells into the patient.

80. The method of claim 79, wherein the number Th2 cells is at least 10^9.

81. The method of claim 79, wherein the cells are contained in a volume of 1 liter or less.

82. The method of claim 79, wherein the Th2 cells are memory cells.

83. The method of claim 82, wherein the Th2 cells are activated ex vivo in the presence of interferon-γ, IL-2, or mixtures thereof, prior to infusion.

84. The method of claim 74, wherein the disease is multiple sclerosis, and the composition is produced by a method, comprising:

collecting mononuclear cells from a multiple sclerosis patient;

expanding the cells under conditions whereby a composition containing an amount of Th3 cells sufficient to ameliorate the symptoms or retard or stop the progression of multiple sclerosis; and

infusing the resulting composition of cells into the patient.

85. The method of claim 84, wherein the number of cells is at least 10^9 cells.

86. The method of claim 84, wherein the cells are contained in a volume of 1 liter or less.

87. The method of claim 84, wherein the cells have a memory phenotype.

88. The method of claim 84, wherein the cells are specific for myelin or encephalitogenic epitopes of myelin antigens.

89. The method of claim 74, wherein the disease inflammatory bowel disease (IBD), and the composition is produced by a method, comprising:

collecting mononuclear cells from an IBD patient;

expanding the cells under conditions whereby a composition containing an amount of Th2 cells sufficient to ameliorate the symptoms or retard or stop the progression of the IBD; and

infusing the resulting composition of cells into the patient.

90. The method of claim 89, wherein the number of cells is at least 10^9 cells.

91. The method of claim 89, wherein the cells are contained in a volume of 1 liter or less.

92. The method of claim 89, wherein the disease is Crohn's disease (CD) or ulcerative colitis (UC).

93. The method of claim 89, wherein the Th2 cells are express integrin, $\alpha 4$, $\beta 7$.

94. A method for suppression transplant rejection, comprising:

collecting mononuclear cells from a patient prior to undergoing organ or tissue transplantation;

expanding the cells under conditions whereby a composition containing an amount of Th2 cells sufficient to prevent rejection of the transplanted organ or tissue; and

infusing the resulting composition of cells into the patient.

95. The method of claim 94, wherein the number of cells is at least 10^9 cells.

96. The method of claim 94, wherein the cells are contained in a volume of 1 liter or less.

97. The method of claim 94, wherein the transplanted tissue are transplanted islets of Langerhans.

98. The method of claim 94, wherein the cells are specific for the alloantigens or for an antigen unique to the transplanted tissue or organ.

99. A method for treating insulin-dependent diabetes mellitus (IDDM), comprising:

collecting mononuclear cells from a patient diagnosed with IDDM or at high risk for developing IDDM;

expanding the cells under conditions whereby a composition containing an amount of Th2 cells sufficient to prevent or retard islet destruction; and

infusing the resulting composition of cells into the patient.

100. The method of claim 99, wherein the number of cells is at least 10^9 cells.

101. The method of claim 99, wherein the cells are contained in a volume of 1 liter or less.

102. A method for treating allergies, comprising:

collecting mononuclear cells from a patient prior to undergoing organ or tissue transplantation;

expanding the cells under conditions whereby a composition containing an number of Th1 cells sufficient to ameliorate the symptoms of the allergy; and

infusing the resulting composition of cells into the patient.

103. The method of claim 102, wherein the number of cells is at least 10^9 cells.

104. The method of claim 102, wherein the cells are contained in a volume of 1 liter or less.

105. The method of claim 102, wherein the cells are specific for one or more allergens.

106. A method for treating infectious diseases or cancers, comprising:

collecting mononuclear cells from a patient prior to undergoing organ or tissue transplantation;

expanding the cells under conditions whereby a composition containing a therapeutically effective number of Th1 cells; and

infusing the resulting composition of cells into the patient.

107. The method of claim 106, wherein the number of cells is at least 10^9 cells.

108. The method of claim 106, wherein the cells are contained in a volume of 1 liter or less.

109. The composition of claim 42, wherein the $CD4^+$ cells are predominantly Th2-cells.

110. The method of claim 1, wherein the cells are $CD4^+$ cells.

111. A method for treating infectious diseases or cancers, comprising: co-infusing therapeutically effective numbers of regulatory and effector cells.

112. The method of claim 111, further comprising co-infusing $CD8^+$ effector cells cytotoxic T lymphocytes (CTLs) that are specific for the pathogen or tumor.

113. The method of claim 111, wherein the regulatory cells are Th1 cells.

114. The method of claim 111, wherein the regulatory cells are specific for the pathogen or tumor.

115. The method of claim 108, wherein the disease is renal cell carcinoma and the antigen is Hsp70.

116. The method of claim 111, wherein the number of cells is at least 10^9 cells.

117. The method of claim 111, wherein the cells are contained in a volume of 1 liter or less.

118. A method of vaccination, comprising

exposing isolated mononuclear cells obtained from a patient to a selected vaccine antigen in the presence of one or more cytokines that induce Th1 cells or Th1-like cells to produce Th1 cells or Th1-like cells specific for the antigen; and

expanding the resulting cells for reinfusion.

119. The method of claim 118, wherein the number of cells is at least 10^9 cells.

120. The method of claim 118, wherein the cells are contained in a volume of 1 liter or less.

121. The method of claim 118, wherein the cells have a memory phenotype.

122. The method of claim 118, wherein the cytokine(s) is (are) selected from IL-12 and IFN-γ.

123. The method of claim 118, wherein the resulting cells are $CD4^+$, $CD8^+$ or a mixture thereof.

124. A method for altering the regulatory balance of immune cells in a human, comprising administering to the human a composition comprising a clinically relevant number of autologous regulatory T-cells.

125. The method of claim 1, wherein at least 10^9 cells are administered.

126. The method of claim 16, wherein at least 10^{10} cells are administered.

127. The method of claim 16, wherein the cells are Th1 cells.

128. The method of claim 16, wherein the cells are Th2 cells.

129. The method of claim 16, wherein the cells are Th3 cells.

130. The method of claim 16, further comprising, administering a clinically relevant number of effector immune cells, wherein the effector immune cells are administered with, before or after administration of the regulatory cells.

131. A method for treatment of human immunodeficiency virus (HIV) infection, comprising administering an effective amount of the composition of claim 42.

132. A method for treatment of human immunodeficiency virus (HIV) infection, comprising administering an effective amount of the composition of claim 44.

133. A method for treatment of human immunodeficiency virus (HIV) infection, comprising administering an effective amount of the combination of claim 45.

134. The method of claim 106, wherein the disease is renal cell carcinoma and the antigen is Hsp70.

135. The method of claim 111, wherein the disease is renal cell carcinoma and the antigen is Hsp70.

136. The method of claim 3, wherein the expanded cells are purified.

137. The method of claim 1, wherein the mammal is a human.

138. The method of claim 2, wherein the mammal is a human.

139. The method of claim 3, wherein the mammal is a human.

140. The method of claim 1, wherein the immune cells are activated ex vivo in the presence of interferon-γ, whereby differentiation of Th1 cells are effected.

141. The method of claim 1, wherein the expanded cells are predominantly Th1 cells, whereby the resulting population has a Th1 or Th1-like cytokine profile.

142. The method of claim 6, wherein the expanded cells are predominantly Th1 cells, whereby the resulting population has a Th1 or Th1-like cytokine profile.

143. The method of claim 7, wherein the expanded cells are predominantly Th1 cells, whereby the resulting population has a Th1 or Th1-like cytokine profile.

144. The method of claim 1, wherein the expanded cells are predominantly Th2 cells, whereby the resulting population has a Th2 or Th2-like cytokine profile.

145. The method of claim 6, wherein the expanded cells are predominantly Th2 cells, whereby the resulting population has a Th2 or Th2-like cytokine profile.

146. The method of claim 7, wherein the expanded cells are predominantly Th2 cells, whereby the resulting population has a Th2 or Th2-like cytokine profile.

147. The composition of claim 42, wherein the cells are contained in a volume of 1 liter or less.

148. The composition of claim 42, wherein the cells are contained in a volume of 500 mls or less.

149. The composition of claim 147 that contains at least about 10^9 cells.

150. A composition produced by the method of claim 41, wherein the cells are contained in a volume of 1 liter or less and the number of cells is at least about 10^9.

151. The composition of claim 150, wherein the cells are contained in a volume of 500 mls or less.

152. The composition of claim 150 that contains at least about 10^{10} cells.

153. A method of treating a patient infected with HIV, comprising administering the combination of claim 45, wherein the compositions are administered simultaneously or sequentially.

add B6

add C1

Add F'